

Dear Mark and Mort,

The following are my comments with regard to the Report on Data from Testing of Human Subjects. I apologize for not getting this information to you sooner but I was out of state for a good part of last week and didn't get the documents until the end of the week. (That's not a very good excuse, I know, but it's better than using my grandchildren as the excuse or stating that the dog ate my homework!)

In general, I found this report to be fascinating. Testing of human subjects is a complex and intensely emotional issue. The Sub-committee did an excellent job of capturing the essence of the ethical and scientific problems. In my review, I have tried to refrain from commenting on the essence of the report but in some cases have not been successful.

The charge to the subcommittee was quite extensive and covered a broad range of technical and ethical issues. The subcommittee addressed the charge questions in detail in most cases but left this reader a bit up in the air in other cases. The first part of the charge involved the value of human studies. The Subcommittee addressed this question completely. The sub-committee also responded in detail to the three issues raised in the second part of the charge, i.e., factors for consideration. In particular, the concise statement as to when testing of human subjects would be appropriate (benchmarks) was expressed very well and unambiguously (page 2 of the letter to the Administrator and other sections of the report).

The first part of charge question c, the risks and benefits to subjects and society was also addressed very well. The second part of that charge question left me a bit up in the air. The recommendation seemed to be that remuneration should not rise to the level that it would be considered coercive. That certainly makes sense; however, on page 30 of the report, the sense that I got from reading from line 10 on was that the subcommittee was suggesting that individuals in poorer communities might receive lesser remuneration for taking the same risks as individuals in wealthier communities. Are "non-exploitive" levels of remuneration, in fact, discriminatory? This issue needs some clarification.

The committee addressed charge questions d, which relates to application to specific situations, and e, which involves the determination as to whether the ethical standards have been met, adequately. The letter to the Administrator and the Executive Summary included many of the important points in the report but did not specifically address the charge questions. It would be helpful to the reader to include at least a brief response specifically to the questions in addition to the general issues included in the letter and summary. One important point that I think was omitted from those two documents is the statement on 33 (lines 23-26) to the effect that data based on research that did not meet current ethical standards should not be rejected on that point alone. However, the statement on page 41 lines 20 - 23 seems to contradict the previous point. This should be clarified.

Two other issues of concern:

1. In the letter to the Administrator, (page 2, lines 11-13) the statement is made that in no case should developing humans (i.e., the fetus, infant, and young children) be exposed to neurotoxic

chemicals. This leaves open to question whether a teenager could be used in such experiments. In other sections of the report, the statement deletes the qualifier "young". While I am sure the Subcommittee discussed this issue and perhaps, I have a big problem with specifying young children and leaving the issue of pre-teens and teenagers in limbo. Perhaps the Subcommittee could be more specific in defining what it means by children and young children.

2. On page 34, lines 7-9, the report states that considerable information has been gained by studying survivors of WWII and Chernobyl? It is somewhat premature to put Chernobyl in the same category as Hiroshima and Nagasaki. In fact the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) 2000 Report, released last week, states that 1800 cases of thyroid cancer in children who were exposed at the time of the accident have been observed. Apart from the thyroid cancer there is no evidence of a major public health impact attributable to radiation exposure. There is no scientific evidence of increases in overall cancer incidence or mortality in non-malignant disorders that could be related to radiation exposure. Lumping WWII and Chernobyl together may give the wrong impression about the consequences of the accident. Perhaps substituting radon daughter effects on lung cancer in underground miners would be more appropriate, at least until more formal studies are available on the impacts of Chernobyl.

On an editorial note: The purpose for the bolding in the report was not always obvious. In some cases most of the paragraph was bolded with parts of sentences not bolded. There are a few other typographical problems that I will convey to you separately.

In all, the Subcommittee took a very difficult subject and did an excellent job.